IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINIONS OF MICHAEL P. WOODS, M.D.

Defendants Ethicon, Inc., Ethicon, LLC and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' Notice of Adoption of their prior filings to exclude the general opinions of Michael P. Woods, M.D. *See* Doc. 2794, 2041, 2043.

INTRODUCTION

Dr. Woods is an obstetrician and gynecologist focusing on treating incontinence, prolapse, and other pelvic floor disorders. Ex. C to Pl's Motion (Doc. 2041), Expert Report at 1. He has been board-certified in obstetrics and gynecology since 1991 and reconstructive surgery since 2013, the first year the certification became available. *Id.* at 1 & Woods CV (attached to Expert Report). Dr. Woods operated his own private practice in Bellevue, Nebraska from 1997-2013. *Id.*

In the 1990s, the Burch Colposuspension was his primary procedure for genuine stress urinary incontinence. Pl's Ex. C, Expert Report at 2; Ex. A hereto, Woods Oct. 5, 2015 Dep. 139:10-140:7. He began using the TVT in 1999 after "monitoring the initial clinical literature, paying close attention to the mesh erosion/exposure rates." Pl's Ex. C, Expert Report at 2. He has performed thousands of procedures with TVT mesh. *Id.* at 5. He is also experienced with

suburethral slings using autologous slings, porcine skin, bovine dura mater, vicryl mesh, Gore-Tex mesh, and Mersilen mesh. *Id.* at 2.

Currently, Dr. Woods works as a urogynecologist for Shenandoah Medical Center in Iowa. *Id.* at 1. A member of the American Urogynecology Society, International Urogynecology Association, and the American Board of Obstetrics and Gynecology, he has presented both nationally and internationally on areas involving gynecology and pelvic floor disorders, including lectures on polypropylene mesh. *Id.*; Ex. A hereto, Woods Oct. 5, 2015 Dep. 87:5-11; 89:4-14.

In these cases, Dr. Woods intends to offer opinions generally addressing the utility and safety of the TVT and TVT-O devices. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other material reflected in his reliance list. Pl's Ex. C, Expert Report at 1-5; Ex. B hereto, Reliance List. His is qualified to opine on these topics and, as detailed below, his opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Woods's opinions, and as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Woods is qualified to render opinions regarding the utility and safety of the TVT and TVT-O devices, and his opinions are supported by reliable methodology.

Plaintiffs claim that Dr. Woods is not competent to "[g]ive design opinions" on the basis that he has inadequate expertise with the design process and product development and because he has been unable to locate certain records that confirm his personal success and complication

rates. Doc. 2043, p. 5. As set forth below, Dr. Woods does not intend to provide design process opinions, and he is well qualified to testify about the safety and utility of the devices.

A. Dr. Woods will not provide design process opinions.

Plaintiffs made this same challenge as part of their motion to exclude Dr. Woods's opinions in the Wave 1 cases. Noting that Plaintiffs' motion is "plagued with confusion about what constitutes a design opinion," the Court correctly found that "Dr. Woods has not expressed any opinions about the process of designing a product." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582231, at *3 (S.D. W. Va. Sept. 1, 2016). Therefore, the Court denied Plaintiffs' challenge to Dr. Woods's design opinions "as moot." *Id.*

The Court should make the same finding in this wave of cases. Dr. Woods does not intend to opine about product design and development, and Plaintiffs' motion should not be construed as challenging Dr. Woods's opinions about the safety and efficacy of TVT or TVT-O.

B. Ethicon's internal product design process documents are irrelevant to Dr. Woods's safety and utility opinions.

Relying exclusively on this Court's opinion in *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), Plaintiffs argue that because Dr. Woods has not reviewed Ethicon's internal documents about its design process, he cannot opine about any issues that touch upon product design. As previously noted by Ethicon and as acknowledged by the Court, Dr. Woods does not intend to offer *any* opinion regarding the adequacy of Ethicon's internal design procedures or Ethicon's compliance with industry standards during the development of the devices. To the extent that Plaintiffs seek to use Dr. Woods's failure to

review certain design process documents as a basis to exclude his opinions about the safety and efficacy of TVT and/or TVT-O, Plaintiffs' motion lacks merit and should be denied.[1]

This Court's decision in *Winebarger* lends no support to Plaintiffs' argument. In that case, Boston Scientific challenged the opinion of the plaintiff's proposed expert, Dr. Bobby Shull, regarding Boston Scientific's failure to "follow its own internal protocols" and its "lack of due diligence in the design and development" of the product in issue. *Winebarger*, at *14. Dr. Shull, however, did not review any documents related to Boston Scientific's standard operating procedures or its design protocols. *Id.* Consequently, this Court held that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures for the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

In contrast to Dr. Shull in *Winebarger*, Dr. Woods does not intend to offer any opinions regarding Ethicon's "internal design procedures," and therefore, it was unnecessary for Dr. Woods to review any of Ethicon's internal documents related to design procedures. In fact, in *Winebarger*, the Court allowed Dr. Patrick Culligan, a defense expert urogynecologist, to opine about the safety and efficacy of the medical device, even though the Court concluded that Dr. Culligan was not competent to testify about mesh design. *Id.* at *33-35. This Court has found that other physicians with surgical experience were competent to offer opinions similar to that of Dr. Woods. *See, e.g., Tyree*, 54 F. Supp. 3d at 550; *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9; *Trevino*, 2016 WL 1718836, at *33.

Plaintiffs have chosen to focus on an opinion Dr. Woods has not offered related to documents Dr. Woods was not even asked to review. Quite simply, Plaintiffs have not shown

[1] Dr. Woods did review certain Ethicon internal documents related to the TVT device. As he explained: "I have reviewed the internal documents; however, I've not allowed anecdotal, non-evidence-based information to affect the safety and efficacy that I was asked to review." Ex. A hereto, Woods Oct. 5, 2015 Dep. at 14:14-23.

and cannot show that a review of Ethicon's internal product design process documents was necessary for any of the opinions that Dr. Woods intends to provide in these cases.

C. The complication and satisfaction rates identified by Dr. Woods are consistent with the rates reported in peer-reviewed medical literature.

Plaintiffs also argue that Dr. Woods should be precluded from "giving design opinions because he relies in part on supposedly low complication rates from his practice; yet these rates exist only in Dr. Woods's head." Doc. 2043 at 8. Ethicon acknowledges that, in its Wave 1 ruling, the Court excluded Dr. Woods's opinions regarding the complication rates in his own practice on the basis that "his complication rates derive entirely from mental estimates and not from accumulated data or patient records." *In re: Ethicon*, 2016 WL 4582231, at *3. Ethicon respectfully suggests that Dr. Woods's opinions about these rates in his own practice are sufficiently reliable and that the Court allow Dr. Woods to testify about such rates consistent with other decisions issued by the Court. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014) ("If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions"); *Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015) (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device"); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same).

Alternatively, the Court, as it did in its Wave 1 ruling, should limit its exclusion of Dr. Woods's opinions to his statements about his own patients' complication rates and patient follow-up rates. To the extent that Plaintiffs' motion could be construed as challenging Dr.

Woods's ability to provide other opinions about the safety and efficacy of TVT and TVT-O beyond his own personal complication rates, it should be denied.

Indeed, Dr. Woods's extensive personal experiences, coupled with his reliance on the medical literature, make him well qualified to opine about the safety and utility of the devices. Dr. Woods is a skilled urogynecologist with over twenty years of experience treating female pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Pl's Ex. C, Expert Report at 1-2. He has implanted over a thousand TVT and TVT-O devices and regularly treats patients for complications related to pelvic surgery. Ex. A hereto, Woods Oct. 5, 2015 Dep. at 11:16-19; 142:18-143:1; 145:19-24. He has participated as a primary investigator in a study of the TVT Secur, which reported positive findings. *Id.* at 46:22-47:22. He also has acted as investigator for studies of Colopast's Altis single incision sling, and on a separate study for a vessel-sealing device for hysterectomy. *Id.* at 62:22-63:5. Further, he has taught histology in medical school and reviewed pathology slides with pathologists. *Id.* at 90:20-23; 91:16-23.

As reflected in his report, and supported by published studies, the rate of mesh exposure for TVT ranges on average from 1-3% in the peer reviewed literature. Pl's Ex. C, Expert Report at 4; *id.* at 31 (Table 16 Ward/Hilton Trial showing erosion in 1 participant; Cody 2003 Systemic Review demonstrating 1.1% tape erosion rate, 1.4% reoperation for incontinence rate); *id.* at 34 (Tamussino (2001) showing 2.4% reoperation rate); *id.* at 33 Table 17 (reflecting various studies and reported rates of complications). Dr. Woods believes his personal success and complication rates to be generally consistent with scientific literature reflecting rates in the upper 80s to low 90s. Ex. A hereto, Woods Oct. 5, 2015 Dep. at 141:8-20; Pl's Ex. C, Expert Report at 3, 30 (noting Debodinance (2002) published 87% objective cure rate and 95% satisfaction rate); *id.* at

34 (citing Schraffordt (2006) demonstrating 24 month objective cure rates from 87.5% to 96%; Nilsson (2012) reporting 89% of patients very satisfied or satisfied; Svenningsen (2013) reporting objective cure rates of 89.9%); *id.* at 35 (citing Liapis (2010) reporting TVT-O results of 82% cured and 7% improved at 4-year follow-up); *id*. at 35-36 (citing Angioli (2010) reporting TVT-O results of 73% cure rate and 78.4% would undergo procedure again at 5-year follow-up); *id*. at 36 (citing Cheng (2012) reporting 92% objective and 90% subjective cure rate at 5-year follow-up; Serati (2013) reporting 90.8% objective and 90.3% subjective cure rate at 5-year follow-up; Lauri Kainen (2011) reporting 86.2% objective cure rate and noting 88.6% would recommend procedure at 5-year follow-up; Athanosiou (2014) reporting 90.3% objective and subjective cure rate in the TVT-0 group at 7.5 year follow-up);[2] *see also id.* at 40 (citing additional studies).

Dr. Woods has applied a sound methodology in formulating his opinions regarding the safety and utility of TVT and TVT-O, and the rates referenced in his report are supported by his thorough review of peer-reviewed publications demonstrating the long term safety of the devices, as well as the repeated endorsements of medical societies. *Id.* at 19-85. His opinions are also supported by his decades of clinical experience and medical training. Although Dr. Woods could not identify documents verifying precise percentages for specific types of complications realized in his practice, that failure does not impact his ability to testify about the safety and efficacy of TVT and TVT-O, as demonstrated by the scientific literature that he has reviewed.

This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion

[2] Copies of these publications may be provided upon request.

that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare). That is precisely what Dr. Woods will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Woods's testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

II. Dr. Woods is qualified to testify regarding the adequacy of warnings.

Dr. Woods has opined on the completeness and accuracy of the TVT and TVT-O IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Pl's Ex. C, Expert Report at 14, 84-85. Plaintiffs do not challenge, or even address, Dr. Woods's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the IFUs because he is not a warnings expert.

Ethicon concedes that Dr. Woods is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings, however, Dr. Woods, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon*, 2016 WL 4582231, at *3. Dr. Woods's report details his extensive experience with the TVT and TVT-O devices, including particular risks and complications he has experienced and researched. Pl's Ex. C, Expert Report at 5. His

extensive clinical experience with the products in issue is supplemented by an incredibly thorough review of the relevant literature and education he has provided to others. *Id.*, *passim*; Ex. C, Reliance List.

As this Court determined in its Wave 1 ruling, Plaintiffs do not appear to challenge Dr. Woods's competency to testify that risks that did not appear on the IFUs were already commonly known to clinicians. *See* 2016 WL 4582231, at *6 n. 2. To the extent that their motion is construed as doing so, any such challenge should be denied. Dr. Woods will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Woods's report shows that his opinions are based on his extensive clinical experience, *as well as* his thorough critique of scientific literature. *See, e.g.*, Pl's Ex. C, Expert Report at 23-25, 28, 59-60 (explaining why he disputes that mesh causes various conditions, such as damage from particle loss or contraction, cytotoxicity, or degradation). *See also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12.[3]

Dr. Woods, as an experienced clinician, is well qualified to testify about complications that are "well-known and obvious to pelvic floor surgeons performing those types of

[3] While this Court has observed that "[a]bsence of evidence is not evidence of absence," *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

procedures," such that they need not be included in an IFU. Pl's Ex. C, Expert Report at 84; *see also id.* at 27 ("All surgical procedures carry the risks of bleeding, infection, scar tissue formation, [and] damage to other organs"). Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F.Supp. 366 (W.D.Pa. 1977) (FDA offered affidavit in misbranding case). Thus, the TVT IFU supplements all the other sources of a surgeon's knowledge.

The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Woods is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Woods. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon

be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Woods's testimony.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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